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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,004	03/06/2000	John Paul Maye	046436-5016	7731
22504	7590	07/05/2005	EXAMINER	
DAVIS WRIGHT TREMAINE, LLP			HENDRICKS, KEITH D	
2600 CENTURY SQUARE			ART UNIT	PAPER NUMBER
1501 FOURTH AVENUE				
SEATTLE, WA 98101-1688			1761	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/520,004	MAYE ET AL.	
	Examiner Keith Hendricks	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 February 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11-16-04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

NOTE: The Examiner for this application has changed. See new contact information at the end of this Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At various points in claim 2, the recited limitations appear:

- “aqueous process medium”
- “hop acid”
- “aqueous alkaline medium”
- “aqueous alkaline hop acid solution”
- “aqueous hop acid solution”
- “process medium”.

However, there are only 3 different physical components of the claim: (1) the starting hop acid, (2) the starting aqueous alkaline medium, and (3) the resultant “aqueous alkaline hop acid solution.” To this point, the method of step (a) of claim 2 recites the addition of “the hop acid” to the “aqueous alkaline medium”, to form an “aqueous alkaline hop acid solution”, while step (b) recites the step of adding an effective amount of the “aqueous hop acid solution” to the “aqueous process medium”. As the hop acid

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component was not previously recited as aqueous, it is unclear as to how the supposedly *resultant* product (“aqueous [alkaline] hop acid solution”) may be added to *itself* (i.e. the product of step (a)). Further, the term “process medium” is not clearly identified as a component previously in the claim, and it is unclear if this is a different component, or represents the same entity as a differently-recited, but same, claim component. Applicant’s claims are confusing and disjointed, lacking in a clear antecedent basis for several terms, many of which are an apparent attempt to indicate the same material at different points in the method, for which multiple and inconsistent designations have been assigned.

Applicant is encouraged to amend the claims to clearly and distinctly point out that which applicant regards as the invention, and to maintain consistency and continuity throughout the claims, both with regard to the independent claim(s), as well as all dependent claims. See also, at least, claims 8-13. It is noted that the current status of the claims renders them difficult to compare against the prior art.

Note: At page 7 of the response, applicant states that “applicants have amended claim 2 to recite “the pH of the aqueous process medium”. This is not deemed persuasive, as such an amendment is not apparent from claim 2.

Claim 13 is indefinite for the recitation of the phrase “the solution of hops acid”. This lacks a clear antecedent basis within the claims. Further, the hops acid component is not indicated to be in solution. It is unclear if this indicates the “hops acid” starting component, or the resultant “aqueous alkaline hop acid solution.” Given this, it is unclear at what point in the method this component is to be cooled.

Similarly, claim 21 is indefinite, as it is unclear if “the process medium” refers to the starting “aqueous alkaline medium”, or the resultant “aqueous alkaline hop acid solution”, or some separate-yet-undefined “process medium”.

Claims 15-19 are indefinite for the recitation of the phrases “the isomerized hop acid”, “the isomerized hop acid or derivative thereof,” “after dilution as an aqueous solution”, and/or “the aqueous solution comprising the isomerized hop acid.” There is insufficient antecedent basis for this limitation in claim 14 from which they depend. Claim 14 only recites the specific use of “an isoalpha acid.” Claims 15-19 thus also improperly extend beyond the metes and bounds of the independent claim. (Note that, for prior art purposes, this set of claims will be examined to the extent and breadth of the independent claim 14 alone).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4-5, 8-12 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Todd, Jr. et al. (US PAT 5,082,975).

Todd, Jr. et al. disclose the “synthesis of hexahydrolupulone... and its use as a selective inhibitor of cell growth and multiplication.” Example 5 describes the “preparation of an aqueous liquid alkaline solution of hexahydrolupulone.” Example 6 discloses the use of hexahydrolupulone in inhibiting *Lactobacillus acidophilus* growth and fermentation in skim milk media. The sentence spanning columns 7-8 states that this compound inhibits *Lactobacillus* species, as well as other bacteria, but not yeast.

Similar treatment of a 10% sugar solution, inoculated with yeast, did not inhibit fermentation. Accordingly, it is evident that the hexahydrolupulone solution may be used to selectively inhibit growth of specific cell lines, for example, the selective inhibition of *Lactobacillus* in the presence of yeast. Moreover, its use in inhibiting *Lactobacillus* infections in the brewhouse will become immediately apparent to one skilled in the brewing art.

Although the hexahydrolupulone may be used as a neutral solution in alcohol or the like, its preferred form is as a stable alkaline solution as described in Example 5.

Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

i) Claims 2-10, 12, 13 and new claim 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newsletter of the Bayside Brewers Club

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(<http://www.home.aone.net.au/bbc/bbcmay.html>, pages 1-7, May 1996) ("Bayside") as evidenced by Haas Products & Applications (http://www.john-i-haas.com/products/getinfo_products.htm?prod=isohop) ("Products"). The references and rejection are incorporated as cited in a previous Office action.

Applicant's arguments filed February 1, 2005, have been fully considered but they are not persuasive. At the top of page 8 of the response, applicant states that the "Products" reference is not applicable prior art, as it was only available subsequent to the filing date of the instant application. This is not deemed persuasive, as this reference was not cited as either part of a combination, or as a direct reference as part of the rejection, *per se*. Instead, it was cited as an evidentiary reference, and as such, is not bound by the statutes regarding publication date. This reference was cited only to support the position of the Office, in order to demonstrate that which was specified in the reference and rejection. Technically speaking, the rejection itself was made over the "Bayside" reference alone. Support in the form of demonstration of a factual element may be relied upon at any point, as was done with the Products reference.

At page 8 of the response, applicant states

Products is also improperly cited if intended to demonstrate that ISOHOP® as used in Example 5 of Applicants' specification is necessarily the identical material to the material designated "Isohop" in Bayside. No such extrapolation can be made. Bayside provides no indication of the nature of their "isohop" material other than it is an "isomerized hop extract" with an "alpha-acid rating of 30%". Bayside provides no teaching or suggestion that their isohop material is in a salt form (while Applicants' claimed methods incorporate salt forms), and provides no motivation for salt forms. In fact, the description in Bayside that the material is "already in the correct form" can be construed to indicate that it is the acid form that is being used in the Bayside isohop material, not Applicants' salt forms.

This is not deemed persuasive for the reasons of record. Regarding the statement that "Bayside provides no indication of the nature of their 'isohop' material", this is exactly the reason the Products reference was included, to demonstrate conclusively that this material is, indeed, the same. This is a trademarked material, commonly used in the industry, just as that utilized by applicant in their specification. If applicant is alleging that the term "ISOHOP" may indicate two or more different materials, then the ISOHOP material utilized in applicant's specification could be placed under the same scrutiny. Unless applicant has specifically and unequivocally identified the exact components, properties, ratios and percentages of their ISOHOP composition (which they have not), then given applicant's own line of reasoning, any results derived therefrom cannot be accepted as enabled, since this composition would be undefined and variable, and the experiments utilized within the specification would not be able to be repeated by one of skill in the art.

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However, for the sake of compact prosecution of the application, the following will be noted. Page 13 (example 5) of applicant's specification utilizes ISOHOP ® and identifies such by indicating "ISOHOP ® (a 30 wt.% aqueous solution of potassium salt isoalpha acid commercially available from Haas Hop Product, Inc.)." This is the exact same company and preparation as utilized by the Bayside reference and the Haas Products & Applications ("Products") reference, absent any clear and convincing evidence and/or arguments to the contrary.

Regarding applicant's statement that "Bayside provides no teaching or suggestion that their isohop material is in a salt form", and that the reference teachings may be "construed to indicate that it is the acid form that is being used in the Bayside isohop material, not Applicants' salt forms," this is not deemed persuasive, as no current claim is limited to – or even recites – the salt form of a hop acid. In fact, in direct conflict with this particular argument, the last line of instant claim 1 clearly states that "the hop acid is in free acid form." Thus, applicant has positively and directly supported the position of the Office regarding the reference and rejection.

Finally, regarding applicant's statement that the reference failed to characterize their method as an "improved process for controlling micro-organisms," this is not deemed persuasive. The resultant effect of the addition of the ISOHOP ® extract composition would inherently be the same in both the referenced method and that of applicant's claims, absent any clear and convincing evidence and/or arguments to the contrary. The reference need not describe and characterize each and every property of their own invention, and this would necessarily be expected to provide the same results. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

ii) Claims 11, and 14-19 and new claim 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admissions (pages 2-4) in view of Products. The references and rejection are incorporated as cited in a previous Office action.

Applicant did not address this rejection in the recent response, and thus it is maintained for the reasons of record.

iii) Claims 1-13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guzinski et al. (WO 97/33971), in view of Hough et al. ("Malting & Brewing Science").

Guzinski et al. disclose the production of alkaline aqueous solutions of hop acid salts in microparticulate form, "which may also contain other hop isoalpha acids such as IA and/or THIA" (where IA are isoalpha acids and THIA tetrahydroisoalpha acids). The initial hop acids utilized are DHIA (dihydroisoalpha acid, or rho-) and HHIA (hexahydroisoalpha acid). Page 4, as well as several of the examples, describe the mixture and combination of these compounds within the solution. "In making a light-stable beer, it is often desirable to add DHIA and/or HHIA to the kettle late in wort boil, so as to provide bacteriostatic protection for the yeast." In light of prior utilization difficulties of various forms of these compounds, "the novel forms of DHIA and HHIA described... provide superior utilization and assurance of their bacteriostatic effect during fermentation, as compared with the prior-art compositions" (mid-pg. 4). Concentrations of the compounds are provided throughout the reference, including page 4. The reference "provides commercially useful concentrated preparations of DHIA and HHIA which are stable as well as easily used in the brewhouse. It also provides stable concentrated mixtures thereof with IA and THIA" (bottom pg. 5). The pH of the solutions are in the range of 9.5-10.5, adjusted with potassium hydroxide.

Hough et al. disclose the general method of brewing, where hops, in the form of "whole cones, freshly minced hops, powder, pellets or extract" are added to wort in a copper kettle. The reference also describes the addition of the hops at the beginning, during and end of a kettle boil. "Many breweries add hops at the beginning of the boil and postpone adding the remainder until part way through the boil" (pg. 511). Table 15.4 discloses that the pH of the wort composition is in the range of 5.06 – 5.2.

Thus, it would have been obvious to one of ordinary skill in the art to have added the alkaline aqueous solutions of hop acids, as described by Guzinski et al., to the wort-containing composition in a brewery method, such as that described by Hough et al. Guzinski et al. specifically recite that these alkaline aqueous solutions are to be "used in the brewhouse", where "the novel forms of DHIA and HHIA described... provide superior utilization and assurance of their bacteriostatic effect during fermentation." Furthermore, the hops acid composition of Guzinski et al. is higher than that of the wort composition of Hough et al. The hops acid salts in solution would inherently be expected to convert to the acid form once in the lower pH composition, in order to provide the stated bacteriostatic effect. Note that the limitation of claim 12 is essentially a process (claim 2), utilizing a "product by process" (claim 12), where the reference still meets the limitations of the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

i) Claims 2-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-40 of copending Application No. 10/361,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the addition of various types of aqueous alkaline hops acid solutions to fermentation media, including brewing and production of alcohol spirits, in order to avoid contamination by undesired microorganisms. Further, the recited method steps do not a patentable distinction between the two.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

ii) Claims 2-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,893,857. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the addition of various types of aqueous alkaline hops acid solutions to fermentation media, including brewing and production of alcohol spirits (which require the presence of sugar in the media for fermentative growth of yeast), in order to avoid contamination by undesired microorganisms. Further, the recited method steps do not a patentable distinction between the two.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



KEITH HENDRICKS
PRIMARY EXAMINER